

10/541749

JC14 Rec'd PCT/PTO 07 JUL 2005

CASE D0304 NP

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July 7, 2005

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

AMLER ET AL.

APPLICATION NO: UNKNOWN

FILED: HERewith

FOR: BIOMARKERS AND METHODS FOR DETERMINING SENSITIVITY  
TO EPIDERMAL GROWTH FACTOR RECEPTOR MODULATORS

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

This paper is being filed concurrently with the application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-3880.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

In accordance with 37 C.F.R. § 1.98 (a)(2)(iii), applicants wish to call the Examiner's attention to the following related applications:

No. 60/535,151 filed on January 7, 2004;

No. 60/556,903 filed on March 26, 2004; and

No. 60/568,073 filed on May 4, 2004.

Copies of these references are enclosed herewith.


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The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

Bristol-Myers Squibb Company  
Patent Department  
P.O. Box 4000  
Princeton, NJ 08543-4000  
609-252-4091

  
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Paul Golian  
Attorney for Applicants  
Reg. No. 42,591

Date: 7/7/05

FORM PTO-1449  
(REV. 7-85)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.  
D0304 NP  
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# INFORMATION DISCLOSURE CITATION

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## U.S. RELATED PATENT APPLICATIONS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	60/535,151	1/7/04	Clark et al.			
	AB	60/556,903	3/26/04	Ford et al.			
	AC	60/568,073	5/4/04	Huang et al.			

## U.S. PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AD	4,943,533	7/24/90	Mendelsohn et al.			
	AE	5,196,446	3/23/93	Levitzki et al.			
	AF	5,558,864	9/24/96	Bendig et al.			
	AG	5,569,588	10/29/96	Ashby et al.			
	AH	5,616,582	4/1/97	Barker			
	AI	5,646,153	7/8/97	Spada et al.			
	AJ	5,656,655	8/12/97	Spada et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION YES NO	
	AK						<input type="checkbox"/>	<input type="checkbox"/>
	AL						<input type="checkbox"/>	<input type="checkbox"/>
	AM						<input type="checkbox"/>	<input type="checkbox"/>
	AN						<input type="checkbox"/>	<input type="checkbox"/>
	AO						<input type="checkbox"/>	<input type="checkbox"/>

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AP	Agrawal, D. et al., "Osteopontin Identified as Lead Marker of Colon Cancer Progression, Using Pooled Sample Expression Profiling", Journal of the National Cancer Institute, Vol. 94, No. 7, pp. 513-521 (2002)
	AQ	Alizadeh, A.A. et al., "Distinct types of diffuse large B-cell lymphoma identified by gene expression profiling", Nature, Vol. 403, pp. 503-511 (2000)
	AR	Alon, U. et al., "Broad patterns of gene expression revealed by clustering analysis of tumor and normal colon tissues probed by oligonucleotide arrays", Proc. Natl. Acad. Sci. USA, Vol. 96, pp. 6745-6750 (1999)

EXAMINER

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**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	2AA	5,679,683	10/21/97	Bridges et al.			
	2AB	5,891,996	4/6/99	Mateo de Acosta del Rio et al.			
	2AC	6,235,883	5/22/01	Jakobovits et al.			
	AD						
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							YES	NO
	AM						<input type="checkbox"/>	<input type="checkbox"/>
	AN						<input type="checkbox"/>	<input type="checkbox"/>
	AO						<input type="checkbox"/>	<input type="checkbox"/>
	AP						<input type="checkbox"/>	<input type="checkbox"/>
	AQ						<input type="checkbox"/>	<input type="checkbox"/>

**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

	2AR	Birkenkamp-Demtroder, K. et al., "Gene Expression in Colorectal Cancer", Cancer Research, Vol. 62, pp. 4352-4363 (2002)
	2AS	Bittner, M. et al., "Molecular classification of cutaneous malignant melanoma by gene expression profiling", Nature, Vol. 406, pp. 536-540 (2000)
	2AT	Blanchard, A.P. et al., "Sequence to array: Probing the genome's secrets", Nature Biotechnology, Vol. 14, p. 1649 (1996)

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

3AA	Brown, P.O. et al., "Exploring the new world of the genome with DNA microarrays", Nature Genetics Supplement, Vol. 21, pp. 33-37 (1999)
3AB	Buckhaults, P. et al., "Secreted and Cell Surface Genes Expressed in Benign and Malignant Colorectal Tumors", Cancer Research, Vol. 61, pp. 6996-7001 (2001)
3AC	Cancer Prevention & Early Detection: Facts & Figures, American Cancer Society, Inc., publ. (2004)
3AD	Carlinfante, G. et al., "Differential expression of osteopontin and bone sialoprotein in bone metastasis of breast and prostate carcinoma", Clinical & Experimental Metastasis, Vol. 20, pp. 437-444 (2003)
3AE	Chepenik, K.P. et al., "Epidermal Growth Factor Coordinately Regulates the Expression of Prostaglandin G/H Synthase and Cytosolic Phospholipase A <sub>2</sub> Genes in Embryonic Mouse Cells", The Journal of Biological Chemistry, Vol. 269, No. 34, pp. 21786-21792 (1994)
3AF	Cockett, M. et al., "Applied genomics: integration of the technology within pharmaceutical research and development", Current Opinion in Biotechnology, Vol. 11, pp. 602-609 (2000)
3AG	Dosaka-Akita, H. et al., "Frequent Loss of Gelsolin Expression in Non-Small Cell Lung Cancers of Heavy Smokers", Cancer Research, Vol. 58, pp. 322-327 (1998)
3AH	Eisen, M.B. et al., "Cluster analysis and display of genome-wide expression patterns", Proc. Natl. Acad. Sci. USA, Vol. 95, pp. 14863-14868 (1998)
3AI	Fry, D.W. et al., "A Specific Inhibitor of the Epidermal Growth Factor Receptor Tyrosine Kinase", Science, Vol. 265, pp. 1093-1095 (1994)
3AJ	Furuuchi, K. et al., "Gelsolin as a suppressor of malignant phenotype in human colon cancer", Tumor Targeting, Vol. 2, pp. 277-283 (1996)
3AK	Glinsky, G.V. et al., "Gene expression profiling predicts clinical outcome of prostate cancer", The Journal of Clinical Investigation, Vol. 113, No. 6, pp. 913-923 (2004)
3AL	Golub, T.R. et al., "Molecular Classification of Cancer: Class Discovery and Class Prediction by Gene Expression Monitoring", Science, Vol. 286, pp. 531-537 (1999)
3AM	Grady, W.M. et al., "Genetic and Epigenetic Alterations in Colon Cancer", Annu. Rev. Genomics Hum. Genet., Vol. 3, pp. 101-128 (2002)
3AN	Harris, I.R. et al., "Regulation of HMG-CoA Synthase and HMG-CoA Reductase by Insulin and Epidermal Growth Factor in HaCaT Keratinocytes", The Journal of Investigative Dermatology, Vol. 114, No. 1, pp. 83-87 (2000)

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**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

4AA	Jacob, K. et al., "Osteonectin Promotes Prostate Cancer Cell Migration and Invasion: A Possible Mechanism for Metastasis to Bone", Cancer Research, Vol. 59, pp. 4453-4457 (1999)
4AB	Khan, J. et al., "Classification and diagnostic prediction of cancers using gene expression profiling and artificial neural networks", Nature Medicine, Vol. 7, No. 6, pp. 673-679 (2001)
4AC	Khan, J. et al., "Gene Expression Profiling of Alveolar Rhabdomyosarcoma with cDNA Microarrays", Cancer Research, Vol. 58, pp. 5009-5013 (1998)
4AD	Kim, J.C. et al., "Coexpression of Carcinoembryonic Antigen and E-cadherin in Colorectal Adenocarcinoma With Liver Metastasis", Journal of Gastrointestinal Surgery, Vol. 7, No. 7, pp. 931-938 (2003)
4AE	Kitahara, O. et al., "Alterations of Gene Expression during Colorectal Carcinogenesis Revealed by cDNA Microarrays after Laser-Capture Microdissection of Tumor Tissues and Normal Epithelia", Cancer Research, Vol. 61, pp. 3544-3549 (2001)
4AF	Lillien, L. et al., "BMP and FGF regulate the development of EGF-responsive neural progenitor cells", Development, Vol. 127, pp. 4993-5005 (2000)
4AG	Lockhart, D.J. et al., "Expression monitoring by hybridization to high-density oligonucleotide arrays", Nature Biotechnology, Vol. 14, pp. 1675-1680 (1996)
4AH	Luo, L.-Y. et al., "Prognostic Value of Human Kallikrein 10 Expression in Epithelial Ovarian Carcinoma", Clinical Cancer Research, Vol. 7, pp. 2372-2379 (2001)
4AI	Luo, L.-Y. et al., "The Serum Concentration of Human Kallikrein 10 Represents a Novel Biomarker for Ovarian Cancer Diagnosis and Prognosis", Cancer Research, Vol. 63, pp. 807-811 (2003)
4AJ	Massi, D. et al., "Osteonectin Expression Correlates With Clinical Outcome in Thin Cutaneous Malignant Melanomas", Human Pathology, Vol. 30, No. 3, pp. 339-344 (1999)
4AK	Miura, K. et al., "Solution structure of betacellulin, a new member of EGF-family ligands", Biochemical and Biophysical Research Communications, Vol. 294, pp. 1040-1046 (2002)
4AL	Moriya, S. et al., "Differential expression of HSP90, gelsolin and GST- $\pi$ in human gastric carcinoma cell lines", International Journal of Oncology, Vol. 5, pp. 1347-1351 (1994)
4AM	Neibergs, H.L. et al., "Genetic Profiling of Colon Cancer", Journal of Surgical Oncology, Vol. 80, pp. 204-213 (2002)
4AN	Notterman, D.A. et al., "Transcriptional Gene Expression Profiles of Colorectal Adenoma, Adenocarcinoma, and Normal Tissue Examined by Oligonucleotide Arrays", Cancer Research, Vol. 61, pp. 3124-3130 (2001)

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

5AA	Pan, H.-W. et al., "Overexpression of Osteopontin Is Associated with Intrahepatic Metastasis, Early Recurrence, and Poorer Prognosis of Surgically Resected Hepatocellular Carcinoma", Cancer, Vol. 98, No. 1, pp. 119-127 (2003)
5AB	Panek, R.L. et al., " <i>In Vitro</i> Pharmacological Characterization of PD 166285, a New Nanomolar Potent and Broadly Active Protein Tyrosine Kinase Inhibitor", The Journal of Pharmacology and Experimental Therapeutics, Vol. 283, No. 3, pp. 1433-1444 (1997)
5AC	Perrais, M. et al., "Induction of MUC2 and MUC5AC Mucins by Factors of the Epidermal Growth Factor (EGF) Family Is Mediated by EGF Receptor/Ras/Raf/Extracellular Signal-regulated Kinase Cascade and Sp1", The Journal of Biological Chemistry, Vol. 277, No. 35, pp. 32258-32267 (2002)
5AD	Rich, J.N. et al., "Bone-related Genes Expressed in Advanced Malignancies Induce Invasion and Metastasis in a Genetically Defined Human Cancer Model", The Journal of Biological Chemistry, Vol. 278, No. 18, pp. 15951-15957 (2003)
5AE	Schena, M. et al., "Quantitative Monitoring of Gene Expression Patterns with a Complementary DNA Microarray", Science, Vol. 270, pp. 467-470 (1995)
5AF	Shipp, M.A. et al., "Diffuse large B-cell lymphoma outcome prediction by gene-expression profiling and supervised machine learning", Nature Medicine, Vol. 8, No. 1, pp. 68-74 (2002)
5AG	Shvartsman, H.S. et al., "Overexpression of kallikrein 10 in epithelial ovarian carcinomas", Gynecologic Oncology, Vol. 90, pp. 44-50 (2003)
5AH	Sonneveld, P., "Multidrug resistance in haematological malignancies", Journal of Internal Medicine, Vol. 247, pp. 521-534 (2000)
5AI	Sørli, T. et al., "Gene expression patterns of breast carcinomas distinguish tumor subclasses with clinical implications", Proc. Natl. Acad. Sci. USA, Vol. 98, No. 19, pp. 10869-10874 (2001)
5AJ	Tanaka, M. et al., "Gelsolin: A Candidate for Suppressor of Human Bladder Cancer", Cancer Research, Vol. 55, pp. 3228-3232 (1995)
5AK	Theocharis, A.D., "Human colon adenocarcinoma is associated with specific post-translational modifications of versican and decorin", Biochimica et Biophysica Acta, Vol. 1588, pp. 165-172 (2002)
5AL	Thomas, R. et al., "Differential Expression of Osteonectin/SPARC during Human Prostate Cancer Progression", Clinical Cancer Research, Vol. 6, pp. 1140-1149 (2000)
5AM	Thompson, J. et al., "CGM2, a Member of the Carcinoembryonic Antigen Gene Family Is Down-regulated in Colorectal Carcinomas", The Journal of Biological Chemistry, Vol. 269, No. 52, pp. 32924-32931 (1994)
5AN	Thompson, J. et al., "Down-Regulation of Carcinoembryonic Antigen Family Member 2 Expression Is an Early Event in Colorectal Tumorigenesis", Cancer Research, Vol. 57, pp. 1776-1784 (1997)

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**OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent pages, Etc.)

6AA	Türeci, Ö. et al., "Computational dissection of tissue contamination for identification of colon cancer-specific expression profiles", The FASEB Journal, Vol. 17, pp. 376-385 (2003)
6AB	Urquidí, V. et al., "Contrasting Expression of Thrombospondin-1 and Osteopontin Correlates with Absence or Presence of Metastatic Phenotype in an Isogenic Model of Spontaneous Human Breast Cancer Metastasis", Clinical Cancer Research, Vol. 8, pp. 61-74 (2002)
6AC	van 't Veer, L.J. et al., "Gene expression profiling predicts clinical outcome of breast cancer", Nature, Vol. 415, pp. 530-536 (2002)
6AD	Wands, J.R. et al., "High Affinity Monoclonal Antibodies to Hepatitis B Surface Antigen (HB <sub>s</sub> Ag) Produced by Somatic Cell Hybrids", Gastroenterology, Vol. 80, No. 2, pp. 225-232 (1981)
6AE	West, M. et al., "Predicting the clinical status of human breast cancer by using gene expression profiles", Proc. Natl. Acad. Sci. USA, Vol. 98, No. 20, pp. 11462-11467 (2001)
6AF	Williams, N.S. et al., "Identification and Validation of Genes Involved in the Pathogenesis of Colorectal Cancer Using cDNA Microarrays and RNA Interference", Clinical Cancer Research, Vol. 9, pp. 931-946 (2003)
6AG	Winston, J.S. et al., "Downregulation of gelsolin correlates with the progression to breast carcinoma", Breast Cancer Research and Treatment, Vol. 65, pp. 11-21 (2001)
6AH	Xiong, M. et al., "Feature (Gene) Selection in Gene Expression-Based Tumor Classification", Molecular Genetics and Metabolism, Vol. 73, pp. 239-247 (2001)
6AI	Yamashita, K. et al., "Clinical Significance of Secreted Protein Acidic and Rich in Cystein in Esophageal Carcinoma and its Relation to Carcinoma Progression", Cancer, Vol. 97, No. 10, pp. 2412-2419 (2003)
6AJ	Yu, L.-R. et al., "Proteome alterations in human hepatoma cells transfected with antisense epidermal growth factor receptor sequence", Electrophoresis, Vol. 22, pp. 3001-3008 (2001)
6AK	Yunes, M.J. et al., "Loss of Expression of the Putative Tumor Suppressor NES1 Gene in Biopsy-Proven Ductal Carcinoma <i>In Situ</i> Predicts for Invasive Carcinoma at Definitive Surgery", Int. J. Radiation Oncology Biol. Phys., Vol. 56, No. 3, pp. 653-657 (2003)
6AL	Zou, T.-T. et al., "Application of cDNA microarrays to generate a molecular taxonomy capable of distinguishing between colon cancer and normal colon", Oncogene, Vol. 21, pp. 4855-4862 (2002)
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